

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

October 21, 2002

**NRC REGULATORY ISSUE SUMMARY 2002-19**  
**NEW MODALITIES TO BE REGULATED UNDER 10 CFR 35.1000**

**ADDRESSEES**

All medical licensees authorized to use byproduct material for therapeutic administration.

**INTENT**

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of how three specific new modalities will be regulated under the revised 10 CFR Part 35, "Medical Use of Byproduct Material." No specific action nor written response is required.

**BACKGROUND**

There are three new modalities currently authorized by the NRC on some specific licenses. These are Y-90 microspheres (e.g., MDS Nordion Y-90 TheraSphere®); liquid brachytherapy (e.g., Proxima Therapeutics' GliaSite® Radiation Therapy System); and intravascular brachytherapy (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

**SUMMARY OF ISSUE**

On the effective date of the revised Part 35, October 24, 2002, Y-90 microspheres, liquid brachytherapy, and intravascular brachytherapy will be governed by §35.1000, based on NRC's determination that they do not fit into §35.100 through §35.600. For licensees currently authorized to use these modalities, their existing license conditions applicable to these types of use will remain in effect after October 24, 2002.

Specific licensees that want to be authorized to use one or more of these new modalities on or after the effective date of the final rule should request license amendments in accordance with §35.1000 and §35.12(d).

**ML022830802**

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

**/RA/**

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Attachment: List of Recently Issued NRC Regulatory Issue Summaries

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OFFICE	MSIB	MSIB	NMSS/Editor	MSIB	IMNS
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LIST OF RECENTLY ISSUED  
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2002-18	Issuance of Orders Imposing Additional Physical Protection Measures for the Transportation of Spent Nuclear Fuel Greater than 100 Grams	10/03/2002	All U.S. Nuclear Regulatory Commission specific power reactor licensees, research and test reactor licensees, independent spent fuel storage installation licensees, and special nuclear material licensees, who possess spent nuclear fuel; and general licensees under 10 CFR 70.20a who transport spent nuclear fuel greater than 100 grams.
2002-14, Sup. 1	Proposed Changes to the Safety System Unavailability Performance Indicators	09/30/2002	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2002-17	Guidance on Performing Military Service Verification	09/19/2002	All holders of operating licenses for nuclear power reactors.
2002-16	Current Incident Response Issues	09/13/2002	All holders of operating licenses for nuclear power plants.
2002-15	NRC Approval of Commercial Data Encryption Systems for the Electronic Transmission of Safeguards Information	08/28/2002	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).
2002-14	Proposed Changes to the Safety System Unavailability Performance Indicators	08/28/2002	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

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